

POCKET NO.: ISIS-4824

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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In Re Application of:

Ching-Leou Teng, et al.

Serial No.: 09/935,316

Filing Date: August 22, 2001

For: BIOADHESIVE COMPOSITIONS AND METHODS FOR ENHANCED  
INTESTINAL DRUG ABSORPTION

Confirmation No.: 1463

Group Art Unit: 1632

Examiner: Not Yet Assigned

#11/R.T.  
11/20  
suppl.  
I.D.S.

DATE OF DEPOSIT: November 12, 2002

I HEREBY CERTIFY THAT THIS PAPER IS BEING  
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TYPED NAME: Emma R. Dailey  
REGISTRATION NO.: 48,491

Assistant Commissioner for Patents  
Washington, D.C. 20231

Dear Sir:

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

Pursuant to 37 CFR § 1.56 and in accordance with 37 CFR §§ 1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 CFR § 1.56(b).

- ☒ In accordance with § 1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified application, within three months of the date of entry into the national stage of the above identified application as set forth in § 1.491, before the mailing date

of a first Office Action on the merits of the above-identified application, or before the mailing date of a first Office Action after the filing of request for continued examination under § 1.114, no additional fee is required.

☐ In accordance with § 1.129(a), this Information Disclosure Statement is being filed in connection with ☐ the first or ☐ second After Final Submission, therefore:

☐ Certification in Accordance with § 1.97(e) is attached; or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(c), this Information Disclosure Statement is being filed after the period set forth in § 1.97(b) above but before the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311, or before an action that otherwise closes prosecution in the application, therefore:

☐ Certification in Accordance with § 1.97(e) is attached;  
or

☐ The fee of \$180.00 as set forth in § 1.17(p) is attached.

☐ In accordance with § 1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under § 1.113 or a Notice of Allowance under § 1.311 but before, or simultaneously with, the payment of the Issue Fee, therefore included are: Certification in Accordance with § 1.97(e); and the submission fee of \$180.00 as set forth in § 1.17(p).

☒ Copies of each of the references listed on the attached Form PTO-1449 are enclosed herewith.

- ☐ Copies of references listed on the attached Form PTO-1449 are enclosed herewith

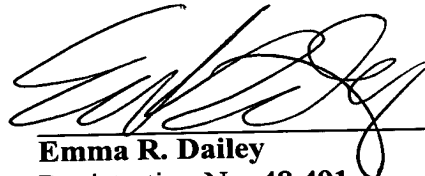
## EXCEPT THAT:

- ☐ In view of the voluminous nature of references [list as appropriate], and the likelihood that these references are available to the Examiner, copies are not enclosed herewith.
- ☐ In accordance with § 1.98(d), copies of the following references listed on the attached Form PTO-1449 are not enclosed herewith because they were previously cited by or submitted to the U.S. Patent and Trademark Office in patent application(s) for which a claim for priority under 35 U.S.C. § 120 have been made in the instant application:
- ☐ Copies of references [list as appropriate] listed on the attached Form PTO-1449 were previously cited by or submitted to the Patent and Trademark Office in prior application Serial No. , filed .
- ☐ If any of the foregoing publications are not available to the Examiner, Applicant will endeavor to supply copies at the Examiner's request.

Please charge any deficiency or credit any overpayment to Deposit Account No. 23-3050. This form is submitted in duplicate.

There are no listed references which are not in the English language.

Date: *November 12, 2002*

  
\_\_\_\_\_  
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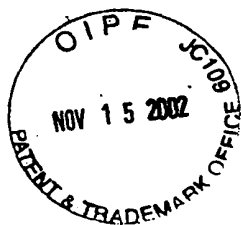
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<b>Form PTO-1449 Modified</b>  List of Patent and Publications Cited by Applicant (Use several sheets if necessary)  U.S. Department of Commerce Patent and Trademark Office		Docket No. <b>ISIS-4824</b>	Serial No. <b>09/935,316</b>
		Applicant <b>Ching-Leou Teng, et al.</b>	
		Filing Date <b>August 22, 2001</b>	Group <b>1632</b>
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>			
	✓ 1	Ahmed, A. et al., "Bioadhesive microdevices with multiple reservoirs: a new platform for oral drug delivery", <i>Journal of Controlled Release</i> , <b>2002</b> , 81, 291-306	
	✓ 2	Duchene, D. et al., "Bioadhesion of solid oral dosage forms, why and how?", <i>European Journal of Pharmaceutics and Biopharmaceutics</i> , <b>1997</b> , 44, 15-23	
	✓ 3	Gu, J-M. et al., "Binding of acrylic polymers to mucin/epithelial surfaces: structure-property relationships" <i>CRC Critical Reviews in Therapeutic Drug Carrier Systems</i> , <b>1988</b> , 5(1), 21-67	
	✓ 4	Kuo, P.Y.P. et al., "Novel systems for controlled delivery of macromolecules", <i>Critical Reviews in Eukaryotic Gene Expressions</i> , <b>1996</b> , 6(1), 59-73	
	✓ 5	Lehr, C-M. "Bioadhesion technologies for the delivery of peptide and protein drugs to the gastrointestinal tract", <i>Critical Reviews in Therapeutic Drug Carrier Systems</i> , <b>1994</b> , 11(2&3), 119-160	
	✓ 6	Ponchel, G. et al., "Specific and non-specific bioadhesive particulate systems for oral delivery to the gastrointestinal tract", <i>Advanced Drug Delivery Reviews</i> , <b>1998</b> , 34, 191-219	
	✓ 7	Shimoda, J. et al., "Bioadhesive characteristics of chitosan microspheres to the mucosa of rat small intestine" <i>Drug Development and Industrial Pharmacy</i> , <b>2001</b> , 27(6), 567-576	
	✓ 8	Woodley, J. "Bioadhesion: New possibilities for drug administration?", <i>Clin Pharmacokinet</i> , <b>2001</b> , 40(2), 77-84	
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**U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	9	RE 33,093	10/17/89	Schiraldi, et al.	424	676
	10	4,713,243	12/15/87	Schiraldi, et al.	424	151
	11	4,948,580	08/14/90	Browning	424	78
	12	5,192,802	03/09/93	Rencher	514	535
	13	5,314,915	05/24/94	Rencher	514	535
	14	5,330,761	07/19/94	Baichwal	424	469
	15	5,364,634	11/15/94	Lew	424	451
	16	5,462,728	10/31/95	Blank, et al.	424	49
	17	5,462,749	10/31/95	Rencher	424	484
	18	5,472,704	12/05/95	Santus, et al.	424	435
	19	5,554,380	09/10/96	Cuca, et al.	424	441
	20	5,614,222	03/25/97	Kaplan	424	489

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO

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**Ching-Leou Teng, et al.**Filing Date  
**August 22, 2001**Group  
**1632****U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	21	5,629,001	05/13/97	Michael, et al.	424	234.1
	22	5,653,959	08/05/97	Tournier, et al.	424	9.32
	23	5,670,138	09/23/97	Venema, et al.	424	52
	24	5,670,163	09/23/97	Cuca, et al.	424	439
	25	5,750,136	05/12/98	Scholz, et al.	424	448
	26	5,770,627	06/23/98	Inoue, et al.	514	772.1
	27	5,783,193	07/21/98	Michael, et al.	424	207.1
	28	5,955,502	09/21/99	Hansen, et al.	514	558
	29	5,989,535	11/23/99	Nayak	424	78.02
	30	6,120,807	09/19/00	Gombotz, et al.	424	501

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO

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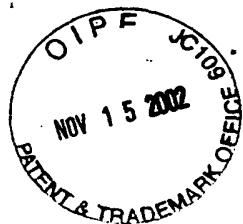


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<b>U. S. PATENT DOCUMENTS</b>							
<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Name</b>	<b>Class</b>	<b>Subclass</b>	
	<b>31</b>	6,123,965	09/26/00	Jacob, et al.	424	489	
	<b>32</b>	6,156,348	12/05/00	Santos, et al.	424	501	
	<b>33</b>	6,200,604 B1	03/13/01	Pather, et al.	424	466	
	<b>34</b>	6,207,197 B1	03/27/01	Illum, et al.	424	491	
	<b>35</b>	6,217,908 B1	04/17/01	Mathiowitz, et al.	424	493	
	<b>36</b>	6,228,383 B1	05/08/01	Hansen, et al.	424	407	
	<b>37</b>	6,242,004 B1	06/05/01	Rault	424	472	
	<b>38</b>	6,248,720	06/19/01.	Mathiowitz, et al.	514	44	
	<b>39</b>	6,274,175 B1	08/14/01	Gombotz, et al.	424	501	
	<b>40</b>	6,280,770 B1	08/28/01	Pather, et al.	424	465	
<b>FOREIGN PATENT DOCUMENTS</b>							
<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Country</b>	<b>Translation</b>		
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**August 22, 2001**Group  
**1632****U. S. PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Name	Class	Subclass
	41	6,303,147 B1	10/16/01	Gilis	424	484
	42	6,355,276 B1	03/12/02	Illum, et al.	424	491
	43	6,368,586 B1	04/09/02	Jacob, et al.	424	78.08
	44	6,375,963 B1	04/23/02	Repka, et al.	424	402
	45	6,387,408 B1	05/14/02	Illum, et al.	424	489
	46	6,391,335 B1	05/21/02	Pather, et al.	424	466

**FOREIGN PATENT DOCUMENTS**

Examiner Initial		Document No.	Date	Country	Translation	
					YES	NO
	47	✓ EP 0 250 187 B1	12/23/87	EPO		
	48	✓ EP 0 449 782 A1	10/02/91	EPO		
	49	✓ EP 0 452 268 A2	10/16/91	EPO		
	50	✓ EP 0 516 141 B1	12/02/92	EPO		
	51	✓ EP 0 526 862 B1	02/10/93	EPO		
	52	✓ WO 91/19486	12/26/91	PCT		
	53	✓ WO 95/26715	10/12/95	PCT		
	54	✓ WO 97/13528	04/17/97	PCT		
	55	✓ WO 97/24109	07/10/97	PCT		
	56	✓ WO 00/35418	06/22/00	PCT		
	57	✓ WO 00/47644	08/17/00	PCT		

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<b>Examiner Initial</b>		<b>Document No.</b>	<b>Date</b>	<b>Country</b>	<b>Translation</b>		
					<b>YES</b>	<b>NO</b>	
	<b>58</b>	✓ WO 02/41765 A2	05/30/02	PCT			
	<b>59</b>	✓ GR 870100935	12/07/87	Greece		X	
<b>EXAMINER</b>				<b>DATE CONSIDERED</b>			